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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,344	01/04/2002	Daniel M. Cimbora	2318-288-II	2255
6449	7590	08/24/2004	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			LANDSMAN, ROBERT S	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/035,344

**Applicant(s)**

CIMBORA ET AL.

**Examiner**

Robert Landsman

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-116 is/are pending in the application.
- 4a) Of the above claim(s) 2-45, 51, 52 and 54-116 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 46-50 and 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>21/12/03</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *1. Formal Matters*

- A. Claims 1-116 are pending and were subject to restriction in the Office Action mailed 6/14/04. IN the Response dated 7/14/04, Applicants elected Group VII, claims 46-50 and 53, with traverse. The response to the traversal appears below.
- B. The Information Disclosure Statement dated 2/12/03 has been entered into the record.

### *2. Traversal*

A. Applicants argue that it is not a serious burden on the Examiner to examine the inventions carved into Groups I-XVI. They argue that all of the claims of Groups I-XVI relate to affecting a protein complex having AKTI. This argument has been considered, but is not deemed persuasive for the reasons already stated in paragraph 2 of Section B of the Restriction mailed 6/14/04. Furthermore,

Inventions VII and I, II, V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product MPEP § 806.05(h). In the instant case the protein complex can be used as antigen for antibody production, the antibody can be used to purify the complex, or can be used therapeutically. Non-human animals can be used for antibody production.

Invention VII is unrelated to Inventions VI, VIII, X, XII, XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. The drugs, compounds and modulators are not used as part of the claimed screening methods.

However, claim 1 will be included in the elected Group. Therefore, claims 1, 46-50 and 53 are the subject of this Office Action. This restriction is deemed proper and is, therefore, made FINAL.

### *3. Specification*

- A. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Methods of using protein complexes in drug screening.

Art Unit: 1647

#### **4. Claim Objections**

- A. Claim 46 is objected to since there should be a colon after the phrase “said method comprising”

#### **5. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- A. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of screening compounds which affect the interaction of the protein complex, does not reasonably provide enablement for a method of screen for compounds which affect any and all physiological disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The breadth of the claims is excessive with regard to Applicants claiming methods of screening for compounds which can potentially treat any and all physiologic disorders. Applicants have not provided any guidance or working examples of compounds which can treat this broad scope of disorders, nor is it predictable to the artisan which compounds would be able to treat any physiologic disorder, nor would it be predictable which disorders would be affected by disrupting a protein-protein complex.

#### **6. Claim Rejections - 35 USC § 112, second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- A. Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. First, the phrase “useful” in the preamble should recite “which can potentially be used.” Second, part (a) is confusing since it says measuring the activity of a protein selected from a first and second protein of

Art Unit: 1647

claim 1. However, claim 1 is a protein-protein complex, not a single protein. It is also not clear if these proteins referred to in part (a) are the same or different. Third, in part (a), the word “goup” should be “group.” Fourth, part (c) should recite “(a) and (b)” not “(1) and (2).”

### **7. Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 1, 46-50 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Giot et al. (US Patent 6,753,314). The claims recite a protein-protein complex and methods of screening drug candidates which can modulate this interaction. The claims also recite methods of screening compounds which can potentially treat physiologic disorders.

Giot teach protein-protein interactions and screening methods to identify modulators of this interaction (Abstract) as well as for use in the potential treatment of disorders (column 120, line 45). Giot also teach the use of antibodies to detect this interaction (column 116, line 30).

B. Ozes et al. (Nature 401 :82-85, 1999) teach that Akt mediates IKKα phosphorylation (Abstract). Therefore, Ozes teach that Akt forms protein-protein complexes since they are kinases and, therefore, must form a complex with the substrate protein to which the Akt is to phosphorylate. The use of antibodies is taught in at least Figure 4.

C. Bonni et al. (Science 286 :1358-1362, 1999) teach that Rsk's such as pp90 form protein-protein complexes since they are kinases and, therefore, must form a complex with the substrate protein to which the Rsk is to phosphorylate. The use of antibodies is taught in Figures 1, 2 and 4.

Art Unit: 1647

**8. Conclusion**

A. No claim is allowable.

***Advisory information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961.

Official papers filed by fax should be directed to (703) 872-9306. Fax draft or informal communications with the examiner should be directed to (571) 273-0888.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-0700.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
August 10, 2004

  
ROBERT LANDSMAN  
PATENT EXAMINER